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ONE HUNDRED TENTH CONGRESS

## U.S. House of Representatives Committee on Energy and Commerce Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN CHAIRMAN

June 26, 2007

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The Honorable Andrew C. von Eschenbach, M.D. Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply.

As part of this investigation, we are reviewing FDA's proposed plan to close seven of its Office of Regulatory Affairs laboratories. To date, Committee staff have reviewed documents that you have provided regarding this proposed closure of laboratories and have met with FDA personnel in Atlanta, Denver, Detroit, Kansas City, New York, San Francisco, and Winchester, MA. As we previously stated in a letter to you, we are very concerned with many aspects of the laboratory closure plan. One particular area of concern is the plan to close the Winchester Engineering and Analytical Center (WEAC).

Among its many capabilities, WEAC is the only FDA laboratory that performs radionuclide analyses of food. This means that WEAC is the only FDA facility capable of detecting radiological contaminants in food products. Further, as part of the Food Emergency Response Network, WEAC is the sole FDA laboratory for radionuclide analysis in event of a nuclear disaster and/or counterterrorist event. WEAC also has a Memorandum of Understanding with USDA/FSIS, whereby WEAC would analyze USDA regulated products for radiological contamination in the event of an actual or threatened act of deliberate contamination of the food supply. To put it mildly, the thought of losing WEAC's capabilities is frightening.

The Honorable Andrew C. von Eschenbach, M.D. Page 2

In order to assist the Committee in its investigation into the adequacy of the efforts of FDA to protect the safety of the Nation's food supply, we request that you provide the Committee with the following information:

- 1. If WEAC is closed, will FDA move WEAC's capabilities to another laboratory?
- 2. If WEAC capabilities are moved, what will be the time interval between closure and movement when the Nation will be unprotected from nuclear threats to the food supply?
- 2. If FDA would move WEAC's capabilities to another laboratory, what laboratory would it move them to?
- 3. How will FDA replace the expertise and experience of those analysts currently working at WEAC who choose not to remain with the Agency?
- 4. Does FDA have a plan to contract out the work currently performed by WEAC? If so, to whom?

Please provide your response and all records relating to the requested information no later than the close of business two weeks from the date of this letter. Please note that, for the purpose of responding to the above request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. After review of your response and the requested records, we may require additional documents and/or staff interviews of FDA personnel.

If you have any questions relating to this request, please contact David Nelson or Kevin Barstow with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,

John D. Dingell

Chairman

Bart Stupak

Chairman

Subcommittee on Oversight and Investigations

## Attachment

cc: The Honorable Joe Barton, Ranking Member Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member Subcommittee on Oversight and Investigations

## **ATTACHMENT**

- 1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, emails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
- 2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.